PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Pub lic Health Council was held on Wednesday, August 8, 2007, 10:15 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Helen R. Caulton-Harris, Mr. Harold Cox, Dr. Michèle David, Dr. Muriel Gillick, Dr. Philip C. Nasca, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Mr. Albert Sherman (arrived at approximately 10:35 a.m.), Dr. Michael Wong, and Dr. Alan C. Woodward. Absent Members were Mr. Paul J. Lanzikos, and Dr. Barry S. Zuckerman. Also in attendance was Attorney Donna Levin, General Counsel, Department of Public Health.

Chairperson Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance . He further announced that the Council would hear the Determination of Need items, the regulations and then the presentation.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF JUNE 13, 2007:

A record of the Public Health Council Meeting of June 13, 2007 was presented to the Council for approval. A copy of the minutes was distributed to the Council Members prior to the meeting for review. Council Member Wong moved for approval. After consideration, upon motion made and duly seconded it was voted unanimously [Council Member Sherman not present to vote] to approve the Record of the Public Health Council Meeting of June 13, 2007 as presented.

Note: The Determination of Need items were heard, right after the Minutes and agenda items #2, 105 CMR 140.000. Licensure of Clinics and #3, Amendments to 105 CMR 800.000, Anatomical Donations were heard later in the meeting, after the Determination of Need items.

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED PROJECT No. 5 - 3A36 OF CAPE COD HOSPITAL, INC.: Request for significant change to increase the project's maximum capital expenditure and number of approved beds :

Ms. Joan Gorga, Director, Determination of Need Program presented the request for significant change by Cape Cod Hospital, Inc. to the Council. She said in part, "… Cape Cod Hospital is before you this morning for significant change to its capital construction project, approved in November of 2002. The hospital is requesting an increase in the maximum capital expenditure and in the number of approved beds, as a result of the planned build-out of the shell space originally approved in 2002. The costs are a result of the construction costs to be incurred in the build-out of two floors of shell space and

some unanticipated costs related to the renovation component of the project. The original MCE for the project adjusted for the 21% inflation and construction costs since that time is forty-eight million, six hundred, twenty-six thousand dollars. The maximum capital expenditure (MCE) is sixty-two million, six hundred and ninety-two thousand, five hundred and thirty-five dollars. The two floors of shell space were constructed with the intent of implementing medical/surgical beds at a later date when funding was available. Shell space is unfinished space and the finishing, or build-out, of that space was not included in the MCE of the original project. Applicants often construct shell space in conjunction with a capital construction project since it is less expensive to do so at that time."

Ms. Gorga further said, "The hospital's fund-raising has been more productive than expected with the help of a significant single donor and matching challenging campaign contributions from others, and the hospital will be able to implement the bed increase earlier than expected. The additional beds will allow the hospital to take out of service beds that do not comply with current standards of square footage per bed and patient privacy issues. Sixty beds will be constructed and forty-five will be taken out of service for a net increase of fifteen beds. Increased costs in renovation include costs identified during the plan review process, costs for new kitchen equipment when the old proved not to be useful any longer, and costs for repairs, the need for which was discovered when walls were opened during the renovation process. Staff finds that the proposed change is reasonable in light of similar past decisions; and, therefore, staff is recommending approval of the request."

Mr. Stephen Abbott, CEO, Cape Cod Hospital, "Our project is a happy project in that our primary benefactor, David Mugar, who gave us the initial gift of five million dollars to begin the project came to us last fall and said he would like to extend the same, a gift, this time a matching gift to finish it…. Since the two floors of thirty beds each were completed this past February, they have been full and have met with great raves from our patients and staff…. Cape Cod hospital has the busiest emergency room in the Commonwealth in the summer. Last year, we had around 83 thousand visits; due to the population swelling from the normal 240,000 a year to six or seven hundred thousand in the summer. This creates more backups in the emergency room with patients waiting to get to a bed. We are hopeful that this will help reduce that situation. What it also does is allow us to take out of service beds that were built back in the 1920s and 1930s, which are really inadequate for today's standards in patient care. We are looking forward to and anticipating completion of these upper two floors in what we call the Mugar Tower that exists as part of Cape Cod Hospital."

Dr. Alan Woodward, Public Health Council Member inquired about the present occupancy rate at Cape Cod Hospital. Ms. Terry Ahern of Cape Cod Hospital said the occupancy rate was 85.3% at the end of July 2007 for adults.

Chair Auerbach said, "I assume that with the increase in the cost, there has also been an increase in the contributions for community health initiatives." Ms. Gorga, Director, Determination of Need Program, responded, "It has not been our habit to return to the

issue of community benefits when there is an increase in the amendment, such as this. So we have not, to date, gone back and reassessed the community initiatives for the increase in the maximum capital expenditure." Mr. Harold Cox, Council Member added, "I am actually glad you raised that question. I am wondering, is that something that we could actually consider. I made an assumption, perhaps wrongly, that it is actually increasing. But it does seem that if there is an opportunity to increase that community health benefit, that we should take advantage of that with the additional request that has been made by the hospital." Chair Auerbach responded, "Would it be possible for us to vote on this particular change with the understanding that the vote is conditional upon an adjustment to the community initiatives budget so that the traditional percentage of the community initiative contributions, relative to capital size are made, and then tha t would be part of the follow-up discussions that occur between staff and hospital? Would that be an acceptable condition?" Ms.Gorga, Determination of Need Director and the applicant, Mr. Stephen Abbott, CEO answered, "Yes".

Council Member Dr. Alan Woodward noted that he wanted to make sure the applicant was not penalized for increased cost of construction that was not anticipated and that inflation was considered. Ms. Gorga noted that the applicant is allowed an inflation allowance adjustment. Chair Auerbach added, "I guess I would say that the principle here may simply be to treat the applicant as we would an y other additional application that had the original amount as the determining amount for calculating the community initiatives effort, and not to do things differently. I think that is what Dr. Woodward was saying. We don't normally require DoNs to recalculate the initiatives based on inflation; but, since this is an increase in the actual capital, initial capital scope of the project, it does seem consistent to have the adjustment made for community initiatives based on that change…"

Dr. Alan Woodward moved approval. After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the request by **Previously Approved Project No. 5-3A36 of Cape Cod Hospital, Inc. for a significant change** to increase the project's maximum capital expenditure and number of approved beds with the Public Health Council's modification as noted above.

Category 1 Application: Project Application No. 5-3B15 of Jordan Hospital: to add Positron Emission Tomography services through acquisition of a PET/CT body scanner .

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program, presented the Jordan Hospital application to the C ouncil. Mr. Plovnick said in part, "… Jordan Hospital is a 114-bed community hospital and has applied for Determination of Need to establish a Positron Emission Tomography service at its campus in Plymouth. Jordan currently contracts for two-day service to be a provider of PET imaging services, operating under a commissioned Letter of Intention in the DoN process. Jordan seeks to replace this contracted service and to provide an expanded PET imaging service on its campus through acquisition of a mobile PE T/CT scanner with an operating lease. The proposed maximum capital expenditure of three million two hundred sixty thousand dollars is based on the fair market value of the equipment. Jordan has attributed its

decision to seek to operate its own PET imaging service to a number of factors including; (1) a growing demand for PET imaging services due to its Oncology and Cardiovascular services growing and the hospital will soon be providing cardiac catheterization services. Jordan believes that providing PET imaging services directly to its patients will best ensure the capacity to meet the growing demand, (2) referring its patients to other hospitals for PET services is not feasible due to the relatively long distance patients would need to travel to access facilities at even the closest hospitals and 3) Jordan believes that providing PET imaging services directly will improve efficiency and service to patients."

Mr. Plovnick further said, "Determination of Need guidelines for PET require that a prospective provider of PET imaging services demonstrate the minimum demand of 1,250 scans per year to its service area population at the time of filing the DoN application. The need analysis involves projecting PET volume from the number of oncology patients served having specific cancer diagnosis and upon the number of cardiac stress tests given with myocardial perfusion. While Jordan's projections feasibly demonstrate reaching the minimum volume requirements by fiscal year 2011, its projected volume in the current year is approximately 1,000 scans or 250 scans below the minimum volume. As a result, staff is recommending that Jordan be granted limited approval to provide PET imaging services on a four day per week basis. If approved, Jordan will not need to file another DoN application to expand to a full time imaging service after its volume reaches 1,250 scans per year. Jordan would merely need to seek an amendment to this project from the DoN program director."

Mr. Plovnick noted that Jordan has an affiliation agreement with Brigham and Women's Hospital, a tertiary teaching hospital as required by DoN Guidelines. In conclusion, he said, "Based upon analysis of all required factors, staff recommends approval of the project with four conditions to this project. The conditions address the project cost, accessibility of services to all regardless of insurance status or inability to pay, interpreter services and a commitment by Jordan to invest $163,000 dollars over five years in support of community health promotion and disease prevention programs serving the hospital's primary service area…."

Mr. Alan Knight, CEO, Jordan Hospital testified next and said in part, "…We are located in Plymouth, MA. We happen to be in the middle of the most rapidly growing area in the state, and also the reality is that cancer rates in our portion of the state tend to be significantly above the state average, and I know if you look at Solucient, they are projecting that, over the next five years, that the rate of cancer incidence will go up by 13.2% over and above what it is now, which is more than five percent above the state average. We do have a very active medical oncology and radiation therapy program at Jordan Hospital, where we see and treat over four thousand patients per year, and actually we have begun our cardiac cath. service just a few months ago and, between our growing cancer volume and our new cardiovascular program, we really have seen the demand for PET/CT services, increasing significantly, to the point where relying on an outside provider really doesn't do the job; and, in light of that current and projected demand, we

think it is in the best interest of our patients to serve them directly, and we are very anxious to integrate the peer review and the quality assurance, etc."

Council Member Harold Cox asked staff to clarify the PHC's job in regards to approving or not approving a PET/CT body scanner and further asked what is so magical about the number of scans 1200 versus 1250 scans. Ms. Gorga, Director, Determination of Need program noted, "I think that part of the issue is to make sure that, if the machine is there it is being used efficiently, and the calculations were that if 1,250 were being done in a year, stretched over a five day week, that that machine would be used efficiently. What we are suggesting here is that 1,000 stretched over a four day week would meet the same conditions. So that it is indeed cost and quality that is involved and the idea is to make sure that there are sufficient machines to take care of the demand, which is an increasing demand, particularly as the machines are primarily used for cancer patients. They are also used on cardiac patients, but primarily on cancer so that this is a growing area, with more and more indications being approved by the Federal Government for the Medicare Program. But to make sure that they are used efficiently, that one thousand two hundred and fifty is calculated to be a measure of efficiency. It is a combination of cost and efficiency."

Discussion followed by the Council. It was noted that Jordan Hospital has been doing 40 scans per month or 500 per year, running a scanner for two days a week. The hospital did not have the number of patients that were referred elsewhere. Mr. Knight said he believed there was another scanner in Weymouth and probably one on Cape Cod. Dr. Muriel Gillick, Public Health Council Member asked if it was possible for the applicant to expand services with their present mobile service provider and if the anticipated PET scanner would be profitable for the hospital. Mr. Knight, CEO of Jordan Hospital responded, "…It is my understanding that this PET/CT scanner, which currently is at our hospital two days a week, is fully booked and not available for additional time, and that is one of the issues, regarding the cost, that is one of the reasons that we would prefer to lease the equipment initially, so that we can size our operations so it does make economic sense, but we recognize that we need more than two. We can certainly get by with four at this point in time, and then we will cut our cost down if the machine can be leased at another place in the meantime. We are very anxious to see this service be under our own license and part of our own peer review and quality assurance process, where currently it is not." It was further noted that Jordan's own radiologists will be reading the scans as they do now. The scanner is expected to run 8 to 10 hours per day being that most appointments are scheduled in advanced for PET/CT since it is not usually an emergency service.

Ms. Brunilda Torres, Director, Office of Multicultural Health, Department of Public Health, responded to a question by Council Member Harold Cox, about the phrase "trained interpreters" that is mentioned in the applicant's conditions of approval. She said that they always use the language "trained interpreters" because they don't want staff to be used and "trained" is the equivalent that the Department has at this point for certification. Ms. Torres said further, "We work very hard with the coordinators and directors of interpreter services to make sure that there is clinical training for people who

do clinical interpretation, and that, for folks, who do logistical interpretation, that there is training on the skills and ethics, and techniques of interpretation. That is why we always insert the phrase "trained medical interpreters."

Dr. Alan Woodward moved approval of the application. After consideration, upon motion made and duly seconded, it was voted unanimously [except Dr. Muriel Gillick abstained] to approve, in part **Project Application No. 5-3B15 of Jordan Hospital**, based on staff findings, with a maximum capital expenditure of $3,260,000(August 2006 dollars) and first year incremental operating costs of $1,572,350 (August 2006). A staff summary is attached and made a part of this record as **Exhibit No.14,885.** As approved this application provides for the establishment of positron emission tomography service through acquisition of a mobile, combination PET/CT body scanner. This approval in part provides for operation of a PET/CT scanner at the campus of Jordan Hospital limited to four days of service per week. This Determination is subject to the following conditions:

1. Jordan shall accept the maximum capital expenditure of $3,260,000 (August 2007 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.

2. Jordan shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.

3. Jordan shall provide a total of $163,000 (August 2007 dollars) over 5 years, or $32,600 per year, to support community programs and projects for prevention services and health promotion in its service area. Such projects will be identified in consultation with CHNA 23 and with the Department's Office of Healthy Communities (OHC). Jordan will work with CHNA 23 and the Department to determine which organization(s) will receive these funds and to ensure that the funds are expended in a productive manner. Jordan has agreed that the funds may be allocated in the following manner:

    a. Mini-Grants awarded through an open, competitive request for responses (RFR) process with preference given to projects/activities that are science based, directed by healthy communities priorities, and targeted toward eliminating racial and ethnic health disparities; and

    b. General community capacity building/program support, including, but not limited to, coalition coordination, training programs and networking opportunities that promote and build in a healthy communities/health disparities framework.

    c. In addition, as requested by the Department, Jordan, in collaboration with CHNA 23 shall file reports detailing its compliance with the approved plan and which will provide an evaluation of the effects of the

programs on the health of residents in CHNA 23.

4. With regards to its Medical Interpreter Service, Jordan shall continue to have in place the following elements of a professional medical interpreter service:

    a. Inform the Limited English Proficiency (LEP) community and service agencies in the Jordan Hospital service area about the availability and provision of interpreter services at no cost.

    b. Maintain signage in the Emergency Department and at all key points of entry into the hospital as required by federal guidelines. Signage must be available in the primary languages identified by the language needs assessment that informs patients of the availability of interpreter services at no charge.

    c. Ensure ongoing training for all hospital clinical staff on the appropriate use of interpreter services.

    d. Enhance its system for tracking, monitoring, and assessing requests for interpreter services.

    In addition, Jordan shall:

    e. Update its policies and procedures to specify the use of only "trained" interpreters.

    f. Develop a plan on how it will use the data collected on race and ethnicity to monitor health disparities.

    g. Conduct an annual language needs assessment and submit a completed report to OMH.

    h. Include the Interpreter Service Manager in all decision-making processes that impact people with LEP.

    i. Follow recommended National Standards for culturally and Linguistically Appropriate Services in Health Care (available online at http://www.omhrc.gov/templates/browse.aspx?lvl=2 &lvlID=15).

    j. Submit to OMH a plan to ensure the inclusion of LEP patients in patient satisfactory surveys.

    k. Submit procedures for translation of written materials to OMH.

l. Notify OMH of any substantial changes to its Interpreter Services Program.

m. Submit a plan for improvement addressing the above within 90 days of DoN Approval to OMH.

n. Provide an Annual Progress Report to the Office of Multicultural Health within 45 days of the end of its fiscal year.

Staff's recommendation was based on the following findings:

1. Jordan proposes to establish a PET service through acquisition of a mobile PET/CT scanner that will operate exclusively at Jordan Hospital.

2. The project meets the requirements of the health planning process consistent with the Guidelines.

3. Jordan has demonstrated demand for the proposed PET/CT service in part, as discussed under the Health Care Requirements factor of the staff summary.

4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.

5. The project meets the compliance standards of the Guidelines.

6. The recommended maximum capital expenditure of $3,260,000 (August 2006 dollars) is reasonable, based upon similar, previously approved projects.

7. The recommended incremental operating costs of $1,456,250 (August 2006 dollars) are reasonable compared to similar, previously approved projects for PET/CT units.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.

REGULATIONS:

REQUEST FOR APPROVAL OF AMENDMENTS TO 105 CMR 170.000, EMERGENCY MEDICAL SERVICES SYSTEM) TO CHANGE T HE INITIATION OF THE TIME PERIOD FOR REINSTATEMENT OF CERTIFICATION OF AN EMT WHOSE CERTIFICATION HAS LAPSED:

Mr. Abdullah Rehayem, Director, Office of Emergency Medical Services, presented the regulation, "We are back before you to request your approval of this technical regulatory change, to change the initial starting point of the one-year period within which an EMT who has allowed their certification to expire to complete all the requirements for reinstatement. You may remember from May when we came to you and presented the reason for the change, three years ago, we changed the EMS regulations to provide the Department with the ability to accredit training institutions and that we moved the responsibility of the practical examination from the Department to the training institution. Prior to that, the Department was in charge of the practical examination. The one-year period began from the date that the Department gave the application for practical exam. Now that we have that accreditation, the applic ant will apply directly to the accredited training program for the practical exam, and we have no idea when that one year begins. We believe that an EMT should complete all their requirements within one year of expiration. The change in the regulations w ill simply change the starting period and will make it one year from the time we get the application for reinstatement, so we have an idea of when that time period begins rather than what it is right now, which is indefinite, and there are no other changes to the reinstatement regulations. We held a public hearing in June and received no oral or written comments. We are again, asking for your approval of the regulatory changes."

Council Member Woodward made the motion for approval. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Request for approval of Amendments to 105 CMR 170.000, Emergency Medical Services System** which change the initiation of the time period for reinstatement of certification of an EMT whose certification lapsed; that a copy be attached and made a part of this record as **Exhibit No. 14,886;** and that the approved amendment be forwarded to the Secretary of the Commonwealth for promulgation.

REQUEST FOR APPROVAL OF AMENDMENTS TO 105 CMR 800.000 (REQUESTS AND CONSENT FOR ANATOMICAL DONATIONS):

For the record: Dr. Michael Wong, Council Member noted for the record that he will recuse himself from this vote.

Attorney Carol Balulescu, Deputy General Counsel, Department of Public Health, presented the amendments to 105 CMR 800.000 to the Council. She said, " I am here today to request Council's approval to promulgate amendments to 105 CMR 800.000., the regulation titled Requests and Consents for Anatomical Donations. The proposed amendments revise the regulation to reflect the recent changes to the Mass. General Laws Chapter 113, Sections 7 through 14. The background on changes in the statute is set forth in a briefing memo provided to you. As noted, the Department held a public comment hearing on June 27th, and the only comments the Department received were from the New England Organ Bank. I have included a copy of that with the memo. The Department is proposing changes that mirror the statutory changes. In summary, no additional consent is required where there is a record of the donor's intent that was not revoked prior to death. The Organ Procurement Organization is acknowledged as the designated requestor, and there is no longer a requirement that hospitals maintain records and report data to the Department. Additionally, in response to a suggestion made by the New England Organ Bank, the Department added the statutory requirements concerning amendment or revocation of the anatomical gift by donor."

Attorney Balulescu acknowledged the assistance of Alexandra Glazier and Sean Fitzpatrick of the New England Organ Bank in drafting and reviewing the regulations.

Dr. Philip Nasca made the motion for approval. After consideration, upon motion made and duly seconded, it was voted unanimously [except for Dr. Wong who recused himself from the vote] to approve the **Request for Approval of Amendments to 105 CMR 800.000 – Request and Consent for Anatomical Donations;** that a copy be attached and made a part of this record as **Exhibit No. 14,887**; and that the amendment be forwarded to the Secretary of the Commonwealth for promulgation. The amendment will take effect on August 24, 2007, the next date of publication in the Massachusetts Register.

PROPOSED REGULATION: INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 140.000, LICENSURE OF CLINICS (LIMITED SERVICE CLINICS):

Dr. Paul Dreyer, Director, Bureau of Quality Assurance and Control, accompanied by Atty. Carol Balulescu, Deputy General Counsel. Dr. Dreyer explained the background on the proposed regulations, the proposed model and the substance of the regulations. He said in part, "…In December 2006, we met with representatives of MinuteClinic/CVS, MinuteClinic being a retail clinic

provider, wholly owned by CVS. They wanted to explore lic ensure of what they call MinuteClinic at a site in Massachusetts; and so, in December of 2006, we met with them to discuss their model and to try to figure out what would be necessary for them to be licensed. We discussed a number of physical environment waivers that might be necessary, but of course no decisions were made at that time. Decisions and discussions were ongoing."

Dr. Dreyer continued, "In the Spring of 2007, we broadened the conversation about this potential new model in Massachusetts to inc lude a number of discussions with various representatives of the medical community. We spoke with representatives of the Mass. Medical Society, Massachusetts Hospital Association, the Mass. Chapter of the American Academy of Pediatrics, and the Mass. Chapter of the American Academy of Family Physicians, Massachusetts Community Health Centers and others about the pros and cons of this model and as a result of those conversations, we decided that the best way to move forward was to amend the current clinic r egulations and create a new category called a 'Limited Service Clinic'."

Dr. Dreyer noted, "The concept of a Limited Service Clinic is certainly not a new idea. Many clinics currently function as limited service clinics. That is , they essentially are licensed as clinics, and they propose to provide a very limited menu of services, and we give them waivers commensurate with the level of services that they wish to provide."

Some examples of limited service clinics are:

- School-based health centers (have p hysical environment waivers, for example, to share a janitor's closet with a school)
- Mobile public health vans
- Nursing sessions in homeless shelters.

Dr. Dreyer noted that the national trade association, "The Convenient Care Association" defines Convenient Care Clinics [others call them Retail Clinics]. "We consider it a subset of a limited service clinic," said Dreyer. The CCA definition is: "It is a small facility, located in high traffic retail outlets with pharmacies that provide affordable, accessible, non-emergent health care to consumers who otherwise would have to wait for an appointment with their primary care physician." Dr. Dreyer stated further:

- CVS operates 229 clinics in 19 states
- The Convenient Care Association includes about 500 clinics in 19 states
- At least 30 states will have these clinics operating
- Wal-Mart plans to open in the next three years an additiona l four hundred of these clinics
- Many of the clinics in other states do not operate as entities licensed by health departments, but rather as physician-owned practices.

Dr. Dreyer noted that they heard from proponents and opponents of the limited service clinics. Below are lists of the noted positive and negative arguments for the clinics:

Positive Comments:

- Increased timely and convenient access to services for patients
- Overcome primary care physician shortages and accompanying delays/difficulties in seeking care
- Positive effect on emergency room crowding (in terms of waiting to be seen) .
- Less inappropriate emergency department utilization

Negative Comments:

- Quality of care issue
- Issuance of multiple waivers questionable (all clinics have waivers so DPH doesn't see as issue)
- Further weakens an already fragmented health care system
- Threatens the relationship between patients and primary care physician
- Offers option to retail outlet not available to non-profit health care providers

Dr. Dreyer further stated, "Our expectations are that the new regulations will address both the process and substantive concerns made by various stakeholder groups and that the Department will engage in a public and transparent hearing process in which everyone can participate."

Dr. Dreyer explained the proposed regulations: "The current clinic regulations have sections of general applicability and there are pages and pages of tables of contents. The new MinuteClinic regulations are down in Subpart K, which is on the third page of the Table of Contents. Everything else applies to what we are proposing with other specific exceptions as noted. Essentially, we are adding a new section to the clinic regulations , Subpart K, which defines a Limited Service Clinic. There is an explicit list of services and treatments. There is a referral in case patients' needs are not consistent with the list. There is physician oversight by a physician off-site. There are no appointments and no waiting – that is one of the strengths of the model."

Dr. Dreyer noted that in developing the Limited Service Clinic regulations they have attempted to comply with the principles of the American Academy of Family Physicians (AAFP). The AAFP does not endorse MinuteClinic or Retail Clinics or Limited Service Clinics as a model but they have said, if there are to be such entities, they need to meet certain standards, and what we have attempted to do is incorporate those standards into the regulations that we have developed. The AAFP recommends and the Department has incorporated these standards into the proposed regulations:

- Limited services clinics must explicitly identify the conditions that they treat.
- Limited services clinics must develop clinical pathways that enable non-physician practitioners to make treatment and triage decisions.
- Limited services clinics must maintain rosters of PCPs (primary care providers) accepting new patients, and provide the roster to patients without PCPs.
- Limited services clinics must fax or email encounter records to patients with PCPs.
- Limited services clinics must see individual patients for no more than a fixed, small number of visits per year.

Further requirements of AAFP and incorporated into the proposed regulations are:

- Limited Clinics must develop policies and procedures to identify the limited services the clinics will provide and the clinic should only provide those services as listed on its license.

- Clinical services and treatment must be evidenced-based and quality improvement oriented. The proposed regulations state that each Limited Service Clinic shall develop policies and procedures that delineate its method for diagnosis, in diagnosing and treating patients, in each of its Limited Service categories and for determining when patients' needs are beyond the scope of the services they provide, essentially clinical pathways.

- Team-based approach: The clinic should have a formal connection with physician practices in the local community and staff should operate in accordance with state and local regulations. The proposed regulation requires that each Limited Service Clinic must maintain a roster of primary care physicians in the clinic's geographic area who are currently accepting new patients, which means that there has to be a positive outreach to those physician practices, and who are willing to accept a referral from the Limited Service Clinic, and each Limited Service Clinic is obligated to describe its staffing pattern in compliance with the over-arching staffing regulations contained in the general applicability section of the regulations.

- There must be a referral pattern, which will result in a referral to physician practices or other entities appropriate to the patient's symptoms when they are beyond the clinic's scope of work, and the clinic must encourage what is called a Medical Home.

- The proposed regulations limit the number of repeat encounters with individual patients. The clinics are for episodic care and not for general routine care. If a patient is going to a Limited Service Clinic too frequently, they need to be referred back to their primary care physician and if the patient does not have a PCP, they must be referred to one.

- Each Limited Service Clinic shall provide a copy of the medical record of each visit to the patient at the end of the visit or as soon as available and to the patient's primary care physician, if any. Such copies shall be provided a t no charge to the patient.

- Dr. Dreyer noted that a public hearing will be held in September, and in October or November they will return to the Council with recommendations that incorporate the changes that are made as a result of the public hearing comm ent process. Assuming the regulations are approved, consideration of applications for the Limited Service Clinic could be in late 2007.

Discussion followed by the Council. Some information provided during discussion follows (for full discussion, please see verbatim transcript of the meeting):

- Limited Service Clinics must specify in their policies and procedures, the number that triggers the clinic to refer a patient to a PCP since the regulations do limit the number of visits a patient may use the Lim ited Service Clinic network per year.

- If an entity wants to obtain a license for a clinic and meets the Department's standards, it gets licensed.

- Retail clinics operate in 38 other states and many are accredited by J CAHO (Joint Commission for Accredita tion of Healthcare Organizations) and also have patient satisfaction data.

- Dr. Philip Nasca suggested that the Department collect baseline data on the Limited Service Clinics.

- If a patient approaches a MinuteClinic for any service that is not on the menu then a referral should be made (including services such as substance abuse and mental health).

- The regulations have an explicit requirement that there be a posting that any prescription that is given to a client of a Limited Service Clinic can be filled at any pharmacy of that client's choosing, not just the pharmacy in which the Limited Service Clinic might happen to be located.

Council Member Dr. Alan Woodward noted, "I think there is no question about what convenience and accessibility are pros for th is concept, and I think the issues of quality and most especially continuity are what you are hearing reflected here. In interjecting a new model, I think what we want to do is err on the side of caution as we go forward here, particularly since there isn't a lot of data on some of the potential impacts. Specifically, I think it is going to be important that we address the concerns of all the groups and I think you have addressed some of the concerns of the American Academy of Family Practice, but I am no t sure that

your regulations are absolutely tied with their recommendations. I think we ought to feed it back to them, and also you mentioned the American Academy of Pediatrics and I know they have had concerns, that they had a couple of additional recommendations, that we look at those. But, I think as we go forward, just conceptually, I would hope that what we do is we err on the side of being cautious, look at pilots, and look at the impact that we are seeing of this kind of transition because it will be a transition. And that we do some monitoring of this, that we do some academic research as to the impact on the health care delivery system, particularly with continuity and integration of care, and quality of care."

Council Member Ms. Lucilia Prates Ramos stated, "…I find this worrisome, and as I look at the time line, this came to your attention in December of 2006. Here we are, August 2007, eight months later, and this is moving right along, like a fast moving train. The fragmentation of care is something that just jumps out at me, and quality. I would like to echo what has already been said, concerns that have already been raised around that. While there may be some positive aspects to this. I think that there are some concerns that I have around access to care for people who are already victims of disparity. How are people who have limited English proficiency going to access services at local CVS clinics or the Wal-Marts? Who is going to translate for them? These are questions that I think we really need to be thinking about very thoroughly. When I think about the policy aspect of this, I mean, we are in a phase of implementation of health care reform in the state of Massachusetts. Who is going to be seeking care at these Limited Service Clinics? Is it those individuals who don't have health insurance, undocumented individuals? Are they going to be, once again, exploited? These are all concerns that I have and that I really think that this Council needs to be really thinking about. Collection of data, I think that that is really important, and that we need to really look at collecting baseline data to really make an accurate analysis of whether or not this should go forth. I am not suggesting that it shouldn't but I think we need to very carefully think about this. I also find it worrisome that we are going to have one public hearing scheduled. I think at the suggestion of Dr. Woodward, we are probably going to have another one, but we need the consumer input. We need to hear from our consumers, who are the victims of the fragmented care that we currently have, and I think we need to be hearing from them when we are making these decisions. I feel very passionate about this."

Council Member Dr. Michael Wong, said he echoed what Ms. Prates Ramos said, also having concerns about fragmentation and disparate populations. Dr. Wong further said that he did some research and found that the data indicates that between 30% and 70% of the populations who use these kinds of facilities are uninsured at least on their initial visit. Dr. Wong further said in part, "This certainly poses a tremendous opportunity, at least right now with the health care reform that are put forth in our Commonwealth, to actually get folks like the Connector involved, and truly establish these folks into care. The concern I have with that, at the same time, are the undocumented individuals who happen to be in our state, where this might actually end up just providing them with an

opportunity for care for a strep throat. That is certainly not entry for management of more significant medical conditions that require true physician evaluations and follow-ups, and all…"

Chair Auerbach summarized, "I am hearing in terms of the kind of feed back that we would like to gather through the public process, a desire to hear about comments with suggestions ensuring that the Limited Service Clinics are appropriately linked to primary care, substance abuse, mental health, and other health care providers so that they don't become isolated providers of care that don't link people to a primary care provider and specialty care. There are questions about whether there should be limits that are set on the type of services that are being provided; for example, whether certain prescription medications should be ruled out as an option, or perhaps whether other services should be ruled out as an option. I am hearing that there is an interest in having people comment on their thoughts with regard to the impact of such regulations on the implementation of Health Care Reform, and on the elimination of racial and ethnic disparities, and specific reference to whether or not those issues will be negatively or positively affected by the regulations, and I am hearing that there is an interest in paying attention to what kind of data and how data could be gathered so that there would be a possibility of reflecting upon what the experience is, both baseline and then after the establishment of such clinics, assuming the regulations are passed."

Chair Auerbach continued, "I am hearing the Council say they would like to see some specific attention paid to the process of putting the regulations out for public comment. One recommendation is that we expand the number of public hearings from a single public hearing to at least two. I assume that the assumption is that they be done in two geographically distinct locations to increase accessibility to people throughout the Commonwealth. I hear that there be an interest in terms of particularly trying to do outreach to solicit a consumer voice at the hearings and not just health care providers or business interests, but also specifically from consumers that may involve advertising or outreach…. Is this guidance for Paul sufficient for the Council to feel comfortable about the process that will begin in terms of soliciting additional feedback before the draft regulations are again brought back to the Council for a full discussion and consideration?"

In closing, Chair Auerbach said in part, "…We look forward to hearing the results of the public hearing process, and we look forward to hearing the specific new dates, and plans to ensure that there is appropriate outreach and opportunities for people." Dr. Dreyer noted that all the public hearing testimony will be available for the Council and public to read verbatim on the DPH website.

NO VOTE/INFORMATION ONLY

PRESENTATION: "HOSPITAL ASSOCIATED INFECTIONS – REPORT FROM THE BETSY LEHMAN EXPERT PANEL":

Chair Auerbach made introductory remarks, "…We are going to be he aring a report that was developed by the Betsy Lehman Center for Patient Safety and Medical Error Reduction. This is an organization that was established in order to focus on those issues, and has made a number of different, previous significant reports a nd recommendations on ways to improve patient safety and the quality of patient care…"

Ms. Nancy Ridley, Director, Bureau of Patient Protection and Director, the Betsy Lehman Center for Patient Safety and Medical Error Reduction, led the presentation. She said, "We are here to present the preliminary findings and recommendations from a study that has been ongoing now for about eight or nine months. It started officially, formally, last November, in terms of the Expert Panel's work. Our researcher, who is also here with us today, Dr. Lisa Hirschhorn, from John Snow Research, was and is one of our most important assets here at the Lehman Center and in the Department of Public Health, in terms of helping us to move forward and accomplish what we are going to briefly describe that we have accomplished… ."

Dr. Alfred DeMaria, expert on infectious diseases, Interim Director of the Department's State Laboratory and Director, Bureau of Communicable Diseases and Control, said in part, "…I think there has been an u nprecedented attention paid to health care-associated infections, and unprecedented concern , which is very welcome by someone who has been doing this for thirty years and by my colleagues. After an initial sort of amazement that it is happening, I think now we are in a period of time when the fact that there are two million of these infections estimated every year, and ninety thousand deaths due to health care-associated infections, it is really getting the kind of attention that we thought it should have gotten for many years, and I don't think we have to spend too much time on defining the problem because the problem has been defined publicly very clearly, and everyone has heard loud and clear that people are not satisfied that this has occurred and is o ccurring."

Dr. DeMaria displayed a map that indicated what other states were doing about infection control. He noted, "I think many of the states are moving in a good direction, and I think Massachusetts is probably moving in the best direction because there has been a conscientious and comprehensive effort at defining the problem and defining what the evidence base is. That is the other thing that I think has been developed over the last ten to fifteen years , is a substantial evidence base on prevention, a substantial evidence base directed at health care-acquired infections. What is also dramatic is how many gaps in that evidence base still exist s and I think we are all, on the Expert Panel, learning what those gaps are and where there are unresolved issues, but where there are resolved issues, there are an enormous number

of recommendations that can be made, that have been shown in the published literature that can reduce health care-associated infections and whenever people think about how realistic this is, this effort towards zero tolerance, and trying to prevent every single preventable health care-associated infection, I think is moving forward, and I don't know if that is achievable. That is obviously controversial, but it is certainly clear that if we can effectively apply these evidence-based recommendations, we can reduce that, and it is clear to my colleagues in the Council of State and Territorial Epidemiologists that, in order to do that, we need an effective surveillance system to monitor outcomes and processes related to those recommendations, and to use that data both to establish the effectiveness of what we are doing, as well as to look at what needs to be done in addition."

Ms. Ridley stated in part, "…In terms of the program goals for and of the program, obviously, these are summarized because, when you see the report, you will see that there are a lot more goals, sub-goals, and objectives that we have, but it was particularly important for us to identify what are the current control and surveillance activities that are going on, not just in the state, but nationally. We needed to access the current definitions for health care-associated infections because that is one of the first things that needed to be standardized in order to compare apples and apples. We wanted to develop cost estimates for Massachusetts that are associated with the impact of health care-associated infections, and the recommendations that we developed, we had two premises. They had to be useful and applicable both to the public, as well as to the institutions, the hospitals themselves …. The actual costs of health care-associated infections to the health care system (third party payers and patients) in Massachusetts is $200 million dollars and 88% of that two hundred million comes from three types of infections:

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- Surgical site infections $87 million
- Bloodstream infections $72 million
- Pneumonia $40 million.

Program Structure:

It was noted that three bureaus of the Department of Public Health are heavily involved in the health care-associated infections (HAI) effort: Dr. DeMaria's programs on Communicable Disease and Control; Ms. Nancy Ridley's Betsy Lehman Center's Expert Panel; and Dr. Paul Dreyer's Health Care Quality Program, the regulatory and mandatory components.

It was further noted that the Betsy Lehman Expert Panel is a multidisciplinary group of 28 members who have met at least once a month for the past eight months. It has six Task Groups:

1. Blood Stream and Surgical Site Infections
2. Optimal Infection Control Program Components
3. Ventilator-associated pneumonia (VAP)

4. MRSA and other selected pathogens
5. Public Reporting and Communication
6. Pediatric and Neonatal

Accomplishments:

- Establishment of Expert Panel
- Organization of six task groups
- Statewide survey of acute care hospitals
- Focus groups with hospital executives
- Formative research with general public
- Analysis of effective educational practices
- Software tools for HAI case finding in hospitals
- Pilot study of simplified definition for ventilator associated pneumonia (VAP)

Ms. Ridley further noted in part, "A statewide survey of all acute care hospitals was also performed, as well as research and analysis of effective educational practices, and there has been the development of some software tools for hospitals to use in case finding, and this was done by some researchers at Brigham & Women's Hospital and it shows a lot of promise for helping to facilitate and expedite hospitals' tasks in being able to find the cases in a lot easier way than has happened previously through electronic medical records…. The hospital survey highlights, there is a lot of detail in the report on it. What is really impressive to me is that we had a 96% return rate from the hospitals: so 68 out of 71 hospitals followed through on the survey. We were heartened to see that virtually all hospitals conducted some form of surveillance for bloodstream, surgical site, and Methicillin Resistant Staph Aureus, and a high percentage were conducting surveillance for some of our specific surgical site areas as well as post-discharge surveillance of patients." Other Hospital Survey Highlights include: Eighty-eight to Ninety-one percent conduct surveillance for total hip replacement, total knee replacement, and post-discharge surveillance for SSI; and that hospitals are engaged in a number of multi-site reporting initiatives:

- Surgical Care Infection Program (SCIP) 90% of hospitals
- Institute for Health Care Improvement Initiatives 85% of hospitals
- Patients First by Mass. Hospital Association 75% of hospitals

Ms. Ridley continued, "There are really two primary findings that we are reporting on: One is the Best Practice or Clinical Guidelines which are adapted from nationally accepted standards of care (Centers for Disease Control (CDC) and the American Thoracic Society) and the second is the reporting which is extremely important, to be able to maintain the recommendations and keep them up to date because it is one of the biggest concerns, that you do a set of recommendations and they are evidence-based when you do them but if you don't maintain them, the technology changes and they become outdated. That is a second component that we are really focusing on with the best practice guidelines."

During her presentation, Ms. Ridley provided the following data: There are, in the report, a total of, at this point, a hundred and thirty-five clinical guidelines or best practices. Those best practices are divided into six areas:

1. Prevention of Ventilator-Associated Pneumonia 20
2. Prevention of Surgical Site Infection 62
3. Prevention of Blood Stream Infections (BSI) 28
4. MRSA 8
5. Standard Precautions 11
6. Contact Precautions 6

Example: Best Practice Guidelines (for Hand Hygiene Recommendations):

1. Do not wear artificial fingernails or extenders when having direct contact with patients at high risk (e.g., those in intensive-care units or operating rooms).

2. Do not wear artificial nails in environments that require sterile conditions (e.g., pharmacies or sterile processing departments).

3. Keep natural nail tips less than 1/4-inch long.

4. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients.

5. Do not add soap to a partially empty soap dispenser. This practice of "topping off" dispensers can lead to bacterial contamination of soap.

6. Encourage patients and their families to remind health care workers to decontaminate their hands in addition to other efforts to improve compliance with hand hygiene.

Ms. Ridley indicated that there are three levels of reporting recommendations (1) to the public (2) to an oversight agency for monitoring and quality improvement and (3) within hospital only, for performance assessment and QI purposes.

Reporting Recommendations of the Expert Panel:

Level I: Reporting to the Public

Outcome measures:

- Bloodstream infections associated with central venous catheters in ICU patients (pathogens)

- Surgical site infections from hip and knee replacements

Process measures:

- Influenza vaccination of healthcare workers (pending final Task Group approval)

Level 2: Reporting to oversight agency

Outcome measures:

- Bloodstream infections associated with central venous catheters in ICU patients – common skin contaminants
- Surgical site infections from CABG and hysterectomy

Process measures:

- VAP prevention – head of bed elevation & daily assessment of readiness to wean
- MRSA point prevalence (pending final Task Group approval)

Level 3: Reporting within hospital only

Outcome measures:

- Bloodstream infections associated with central venous catheters outside of ICU's (pathogens and common skin contaminants)
- Rates of ventilator-associated pneumonia

In closing, Ms. Ridley noted the next steps:

- Dissemination of Expert Panel Recommendations
- Resume Expert Panel monthly meetings in September to complete update of HAI prevention "best practice" guidelines
- Establish a timeline and process for phased-in reporting of the selected measures
- Provide support to hospitals for adoption of best practices and reporting
    - Learning collaboratives, tool kits, educational sessions, technical assistance mini grants
- Examine ways to evaluate and address disparities related to health care-associated infections

Dr. JudyAnn Bigby, Secretary, Executive Office of Health and Human Services, addressed the Council. She said, "…I think that the report will influence many things that we do as we look across the many systems in the State where this could have an influence. I want to acknowledge that I think that this whole issue of preventing and eventually eliminating health care-associated infections is very important. In states where there have been initiatives, we already know that it is possible and people are saving millions of dollars. I think it is very important that we think about that and remind ourselves this is not lost revenue to institutions. It is the opportunity to capture dollars and use them for things that are more appropriate than treating things that should be prevented. As I think about the implications of these recommendations that are going to come out, and how we think about them, there is an opportunity. Most of the presentation that Nancy focused on talked about hospitals. We have state-owned facilities where we should be looking very closely at this. We have the opportunity already to implement standards and procedures that would address this. We operate and oversee many state-owned and -vendored residential facilities where this can have a huge impact in terms of preventing hospitalizations in some of our most vulnerable populations. We also have the opportunity to look at how this relates to nursing homes and other facilities. I just thing it is important for people to understand the importance of the breadth of these recommendations."

Secretary Bigby continued, "I want to acknowledge that one of my goals as Secretary is for our agencies and various bodies to think about how we deliver services and develop policies and procedures that are not in silos but, coordinated. I am very pleased to acknowledge that the Health Care Quality and Cost Council chose as one of its important quality goals, to reduce and eventually eliminate health care-associated infections. It is wonderful to have the work that you have done to help guide how that will be implemented. We were required, as part of Chapter 58, to initiate Pay-for-Performance measures in our Medicaid program as part of a rate increase for hospitals that will be announced officially sometime in the next two weeks, and as one of the Pay-for-Performance measures, we have looked at preventing infections as one of the reporting mechanisms, and one of the things that we are proposing that hospitals be rewarded with the enhanced rates. The work that needs to be done in collaboration with institutions, with leaders, to make these a reality can't be overemphasized. We know that it takes a lot of systems change to get individuals to buy into this, but I actually think the time is right, and that our colleagues all over the state are interested in working with us on these types of things."

Discussion followed by the Council. Council Members Mr. Albert Sherman, Dr. Michael Wong, Dr. Michèle David, Dr. Alan Woodward and Ms. Lucilia Prates Ramos spoke in favor of the report and it dissemination. They further thanked staff responsible for the report, for all their work and dedication to the cause of eliminating or reducing health care-associated infections (see verbatim transcript for full text).

In closing, Chair Auerbach stated in part, "…I would like to thank the Lehman Center and Secretary Bigby in terms of where do we go from here with regards to the next steps to take those recommendations and convert them into specific actions, and I speak on behalf of the Department to say that we fully are committed to joining with you in terms of the ways that we can implement these and be supportive of an overall effort to work on these in terms of promoting quality and reducing cost. I would ask the presenter if you could perhaps come back, and then perhaps, Secretary Bigby, you or your designee could, in a few months come back and give us an update on where we are in terms of having these recommendations finalized, and then we will begin a series of very concrete and specific activities, including the ones that you mentioned with regard to providing support to hospitals and perhaps a campaign of sorts and the Secretary referred to the Council on Quality and we can hear what those activities will involve, as well. I think you clearly heard from the Council Members a commitment to pay attention to this issue on an ongoing basis, and I think we are all eager to think about what role we, as a Council, might have in doing that..."

Council Member José Rafael Rivera noted that September is National Recovery Month – "Celebrate Recovery."

The meeting adjourned at 12:30 P.M.

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John Auerbach, Chair

LMH